



EDUCATIONAL RESOURCES

Drug Supply Chain Security Act

Title II of the Drug Quality and Security Act

Overview of Product Tracking and Tracing Requirements

 PHARMACY



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Objectives & Program Intent

- Discuss the history of the Drug Supply Chain Security Act (DSCSA)
- Understand the timeline of the DSCSA
- Understand the impact on Dispensers and requirements for compliance and reporting
- Understand how to obtain a Global Location Number (GLN)

Agenda Items for Discussion

- History of DSCSA and key requirements and regulations related to the implementation
- Impact of prevalence of counterfeit drugs into the drug supply chain
- Understanding the major provisions of the DSCSA and impact on dispenser's workflow
- Strategies to effectively manage compliance challenges related to the DSCSA
- Key dates and milestones related to DSCSA
- Best Practices for implementing DSCSA workflow at your location

Prescription Safety According to WHO

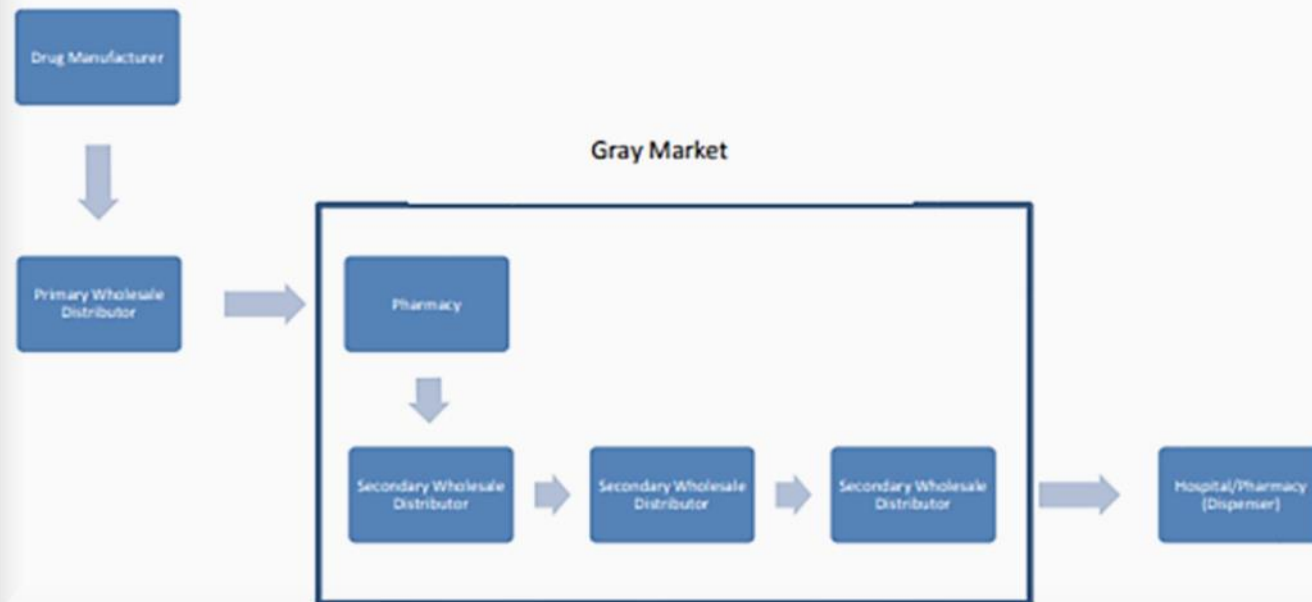
220 billion global
drug counterfeit
market



Figure 1: Typical Drug Distribution Model



Figure 2: Gray Market Drug Distribution Model



How the NECC Case Changed Compounding Pharmacy

- 2012 New England Compounding Center Incidence
 - 64 Deaths
 - 753 sickened
- Fungal meningitis as the result of tainted steroid injections compounded
- A compounding pharmacy making thousands of doses
- This tragedy initiated the passage of the Drug Quality and Security Acts (DQSA) by Congress in 2013
 - 503A
 - 503B
- USP 795 and 797 formally incorporated into regulations

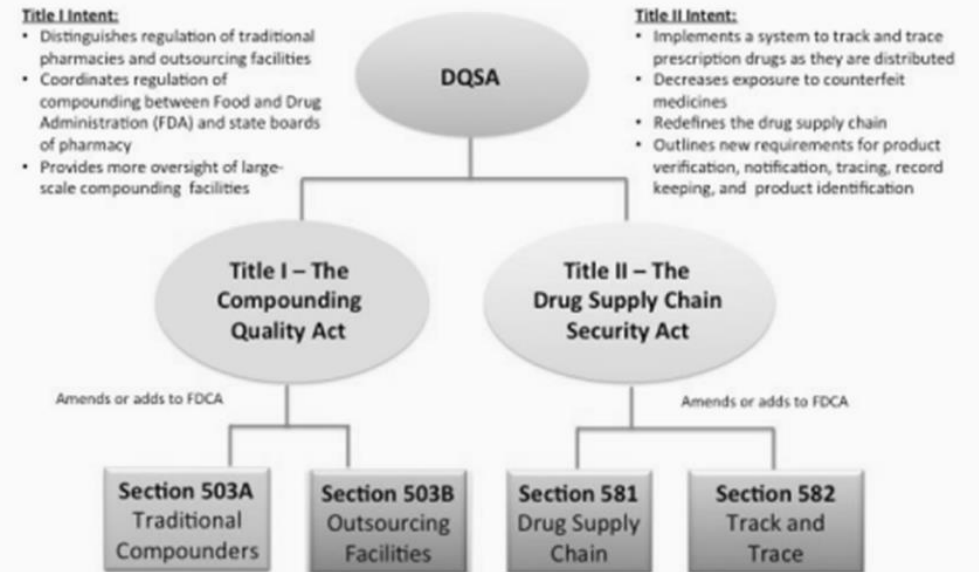
Poll Question #1

- What strategies have you used in the past 12 months when confronted with supply chain related drug shortages?
 - Use secondary or tertiary wholesalers who may charge more.
 - Ration the use of the drug to certain patient populations or adjusted dosage regimen
 - Substitute when possible a therapeutic alternative
 - All of the above

In the Beginning...

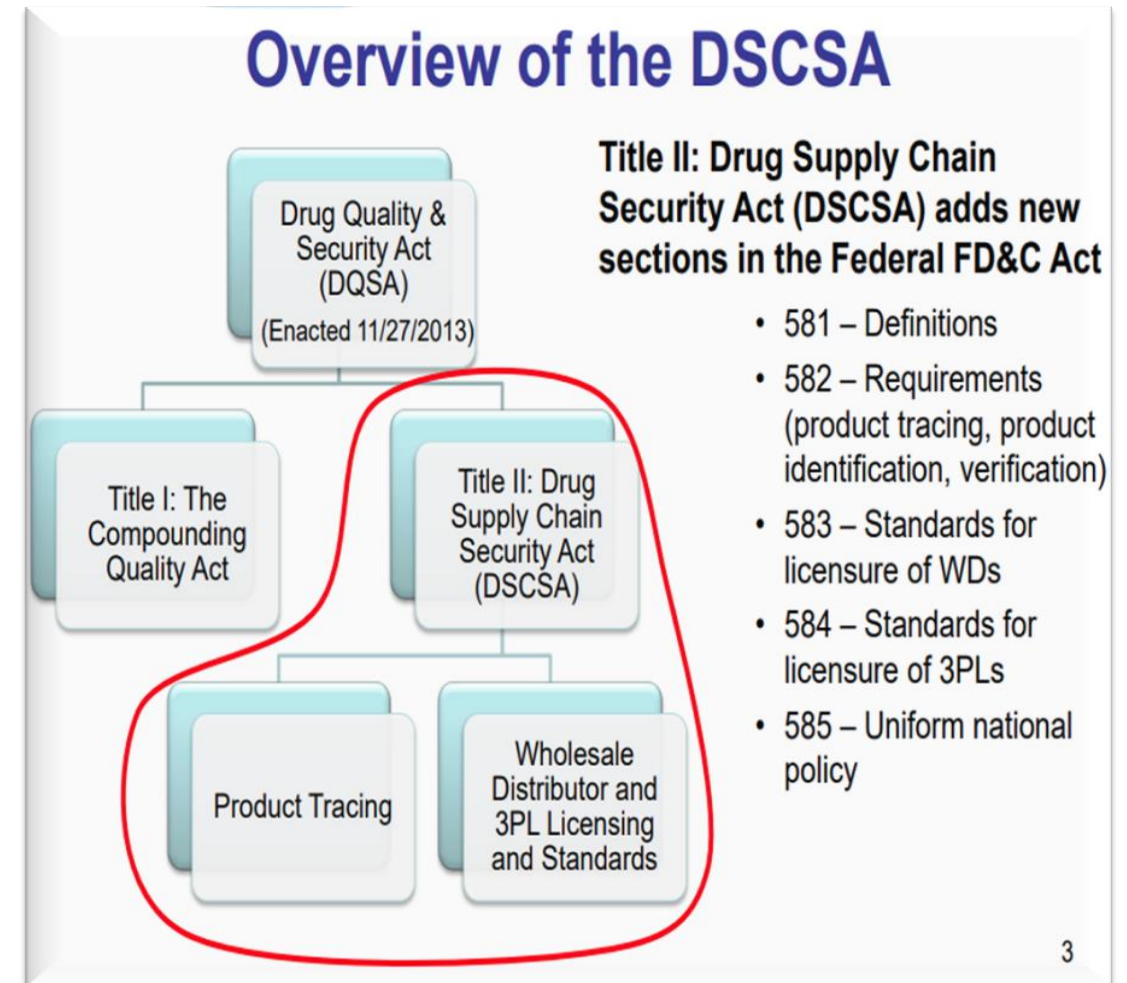
- Drug Quality and Security Act (DQSA) signed into law on November 27, 2013
- Came about as the result of the NECC tragedy and the dangers of unregulated large-scale compounding
- Title 1- The Compound Quality Act
 - 503A
 - 503B
- Title 2- The Drug Supply Chain Security Act
 - “Track and Trace”

Figure 1. The Drug Quality and Security Act of 2013 (DQSA)⁶⁻⁹



DSCSA – What is it?

- Track and trace of products to protect the integrity of the drug supply chain.
- Goes into effect for dispensers on November 27, 2023.
- Pharmacies are considered “dispensers” and are required to have a GLN in order to place and accept orders from trade partners.
- Dispensers need reporting and serialization processes in place to track and trace physical inventory received.



DRUG SUPPLY CHAIN SECURITY ACT

IMPLEMENTATION TIMELINE

NOVEMBER 27, 2013:
Congress enacts
the DSCSA

2013

2014

2015

2016

2017

NOVEMBER 27, 2017:
Manufacturers serialize product

2018

NOVEMBER 27, 2018:
Repackagers serialize product

2019

NOVEMBER 27, 2019:
Distributor traceability

2020

NOVEMBER 27, 2020:
Dispenser traceability

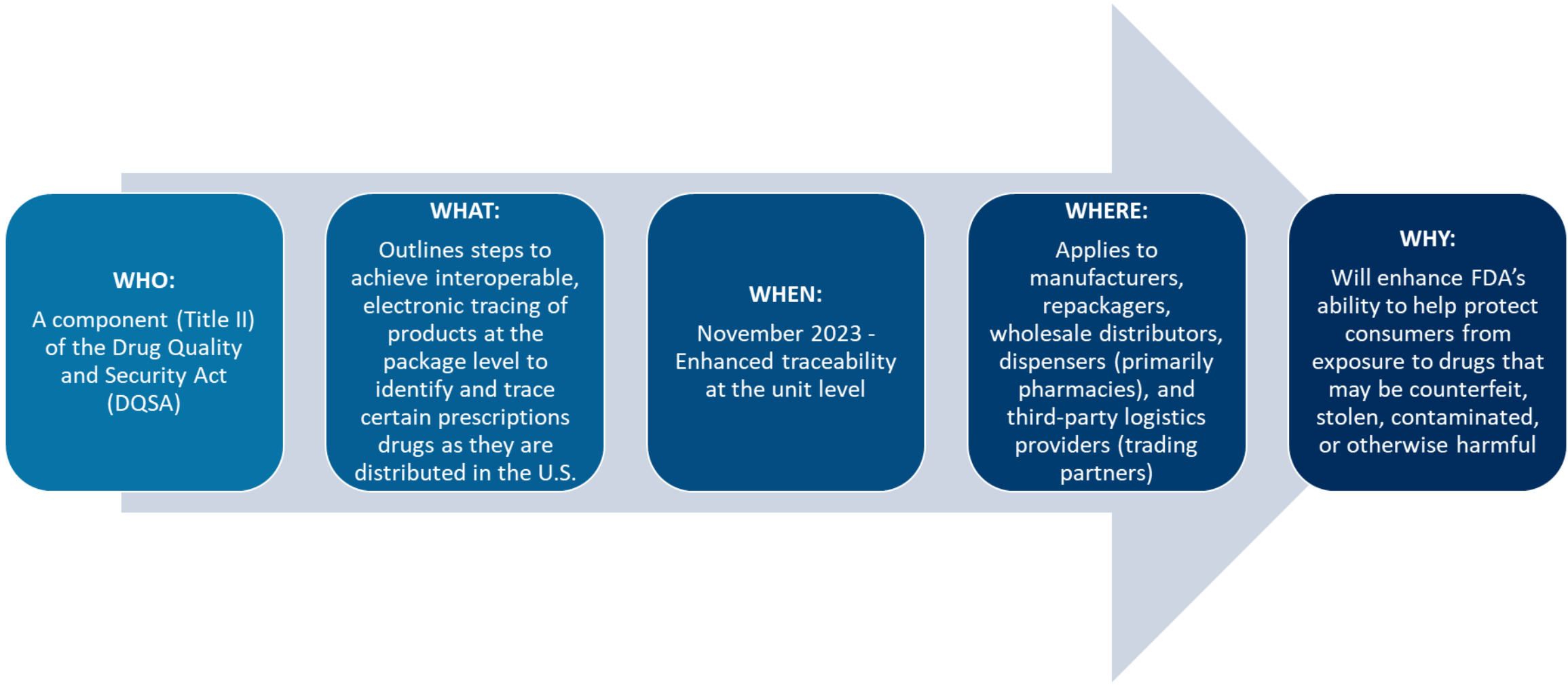
2021

NOVEMBER 27, 2023:
Unit-level traceability

2022

2023

DSCSA Overview



Poll Question #2

- How is your pharmacy accessing DSCSA compliance data today?
 - Through Advanced Shipping Notification (ASN)
 - Wholesaler or distributor Web portal
 - I am unsure

Product Tracing

- Beginning 11/27/2023, dispensers in the drug supply chain must exchange information about a drug and who handled it each time it is sold in the U.S. market.
- Manufacturers, repackagers and wholesale distributors – began 1/1/2015.
- For each transaction, “product tracing information” should be exchanged. Product tracing information consists of the 3 T’s:
 - Transaction information (TI) (which include lot number of product, except for certain wholesale drug distributor transactions)
 - Transaction history (TH)
 - Transaction statement (TS)



Stakeholders Involved

- Dispenser
- Manufacturer
- Repackager
- Third-party logistics provider
- Wholesale distributor
- FDA
- State officials
- International regulatory counterparts
- Others

Definitions (Section 581 of the FD&C Act)

- Dispenser
- Distribute
- Illegitimate product
- Manufacturer
- Package
- Product
- Product identifier
- Quarantine
- Repackager
- Return
- Standardized numerical identifier
- Suspect product
- Trading partner
- Transaction
- Transaction history
- Transaction information
- Transaction statement
- Wholesale distributor
- Among others...

Definitions Cont.

Dispenser

- Retail pharmacy
- Hospital pharmacy
- A group of chain pharmacies under common ownership and control that do not act as a wholesale distributor.
- Any other person authorized by law to dispense or administer prescription drugs and the affiliated warehouses or distribution centers of such entities under common ownership and control that do not act as a wholesale distributor.

Drug Supply Chain Security Act (DSCSA)

- Establishes a federal system for tracing prescription drug products at the individual product level through the pharmaceutical distribution supply chain and requires trading partners to pass, receive and maintain certain product and distribution information.

Electronic Product Code Information Services (EPCIS)

- EPCIS standards define a data model and a data-sharing interface that enables supply chain partners to capture and communicate data about the movement and status of objects in the supply chain.
- EPCIS breaks down supply chain business processes into individual steps such as commissioning, packing, shipping, receiving and provides a standard language in which a party carrying out one of these steps can communicate the essential business information about that step to trading partners who need to know the “what, when, where, and why” of each step.
- Each step is called an “event”, and the term “EPCIS event” refers to the data record that describes an event using the standard EPCIS language.

Definitions Cont.

Global Location Number (GLN)

- A GLN is the globally unique GSI Identification Number used to identify parties and locations. The GLN can be used to identify a legal entity (like a health system), a functional entity (like a pharmacy dispenser or accounting department), or a physical location (like a distribution center, hospital wing, loading dock door, storage location or nursing station).
- GLNs are globally unique and interoperable. They use a common language that can be shared across trading partners to accurately and uniquely identify specific locations.
- Using GLNs can help improve visibility into product location at any point in the supply chain. GLNs are used by manufacturers, distributors, hospitals, end-user locations.

GSI – GSITM

- GSI is a neutral, not-for-profit, global organization that develops and maintains the most widely used supply chain standards system in the world. GSI Standards improve the efficiency, safety and visibility of supply chains across multiple sectors. With local member organizations in over 110 countries, GSI engages with communities of trading partners, industry organizations, governments and technology providers to understand and respond to their business needs through the adoption and implementation of global standards. GSI is driven by over a million user companies, which execute more than six billion transactions daily in 150 countries using GSI Standards.

Interoperability

- Interoperability refers to the ability to exchange transaction history, transaction information and transaction statements accurately, efficiently and consistently among trading partners; and for a subsequent purchaser's system, process or practice to successfully capture and maintain the transaction history, transaction information and transaction statements.

Definitions Cont.

Interoperability Cont.

- Beginning November 27, 2023, electronic based approaches are required to be used among all trading partners to meet the enhanced drug distribution security requirements. Trading partners will be required to use secure, interoperable, electronic approaches to:
 - Exchange transaction information that includes package level product identifiers for each package included in transactions and transaction statements.
 - Verify products at the package level.
 - Facilitate the gathering of transaction information for a product going back to the manufacturer in the event of a recall or for investigations.
 - Accept saleable returns under appropriate conditions.

Product

- A prescription drug in a finished dosage form for administration to a patient without substantial further manufacturing, such as capsules, tablets and lyophilized products before reconstitution.
- A product does not include blood or blood components intended for transfusion, radioactive drugs, imaging drugs, certain intravenous product, any medical gas, homeopathic drugs or compounded drugs.

Transaction Information (TI)

- TI includes the name or names of the product; the strength and dosage form of the product; the National Drug Code (NDC); the container size; the number of containers; the lot number of the product; the date of the transaction and the date of the shipment, if more than 24 hours after the date of the transaction; the business name and address of the person from whom ownership is being transferred; and the business name and address of the person to whom ownership is being transferred.

Definitions Cont.

Transaction History (TH)

- TH represents the transaction information for each prior transaction going back to the manufacturer of the product.

Transaction Statement (TS)

- TS is the statement, in paper or electronic format, that states the partner is authorized to transfer ownership, received the product from an authorized entity, received the TI and TS form the prior owner of the product, did not knowingly ship a suspect of counterfeit product, had systems and processes in place to comply with verification requirements, did not knowingly provide false TI, and did not knowingly alter the TH. This statement may be abbreviated to “Seller has complied with each applicable subsection of FDCA Sec. 581(27)(A)-(G).”

Web Portal

- Option for customers to receive DSCSA serialized TI TS electronically if they do not have the system capabilities to accept EPCIS messages, to receive, store and access DSCSA transaction data.

Poll Question #3

- How will your pharmacy receive DSCSA transaction after 11/27/23?
 - EPCIS Solution Provider
 - Wholesaler or distributor Web portal
 - I am unsure

Definitions: Transaction Information, Transaction History, and Transaction Statement

Transaction Information (TI):

- Proprietary or established name or names of the product;
- Strength and dosage form of the product;
- National Drug Code number of the product;
- Container size;
- Number of containers;
- Lot number of the product;
- Date of the transaction;
- Date of the shipment, if more than 24 hours after the date of the transaction; and
- Business name and address of the person from whom and to whom ownership is being transferred.

Transaction History (TH): A statement in paper or electronic form, including the transaction information for each prior transaction going back to the manufacturer of the product.

Transaction Statement (TS):

A statement, in paper or electronic form, that the entity transferring ownership in a transaction—

- Is authorized as required under DSCSA;
- Received the product from a person that is authorized as required under DSCSA;
- Received transaction information and a transaction statement from the prior owner of the product, as required under the law;
- Did not knowingly ship a suspect or illegitimate product;
- Had systems and processes in place to comply with verification requirements under the law;
- Did not knowingly provide false transaction information; and
- Did not knowingly alter the transaction history.

Scope of the law*

Product

- What's covered:
 - Prescription drug in finished dosage form for administration to a patient without further manufacturing (such as capsules, tablets, lyophilized products before reconstitution)
- What's not covered:
 - Blood or blood components intended for transfusion
 - Radioactive drugs or biologics
 - Imaging drugs
 - Certain IV products
 - Medical gas
 - Homeopathic drugs
 - Lawfully compounded drugs

Transaction

- Transfer of product where a change of ownership occurs
- Exemptions
 - Intracompany distributions
 - Distribution among hospitals under common control
 - Public health emergencies
 - Dispensed pursuant to a prescription
 - Product sample distribution
 - Blood and blood components for transfusion
 - Minimal quantities by a licensed pharmacy to a licensed practitioner
 - Certain activities by charitable organizations
 - Distributions pursuant to a merger or sale
 - Certain combination products
 - Certain medical kits
 - Certain IV products
 - Medical gas distribution
 - Approved animal drugs

Anticipated Dispenser Impacts

- Wholesalers will send DSCSA Transaction Data (including GTIN, serial number, lot and expiry) to downstream trading partners via EPCIS* (replacing today's ASN).
- Dispensers will need a standard location identifier called a Global Location Number (GLN) to receive the serialized transmissions.
- The reconciliation of serialized data with physical product and exception handling processes.
- Wholesalers can only accept a product return into saleable inventory if they sold that specific GTIN, serial number, lot and expiration date to the customer.
- Dispensers need systems and processes for the verification of product and be able to respond to FDA/regulatory requests in the event of a recall or for investigating suspect or illegitimate product.

* Electronic Product Code Information Services (EPCIS) is a GSI international standard that enables trading partners to share information about product as it moves through the supply chain

Anticipated Dispenser Impacts



Wholesalers required by law to send DSCSA transaction data (including global trade items numbers [GTIN], serial number, lot, and expiry) to trading partners via electronic product code information services (EPCIS).



Dispensers (pharmacies) need a standard location identifier called a global location number (GLN) to receive the serialized transmissions.



The reconciliation of serialized data with physical product and exception handling processes.



Dispensers (pharmacies) need systems and processes in place for the verification of product at the package level and be able to respond to requests from the FDA or other regulatory bodies in the event of a recall or for investigating suspect or illegitimate product.

DSCSA Major Provisions

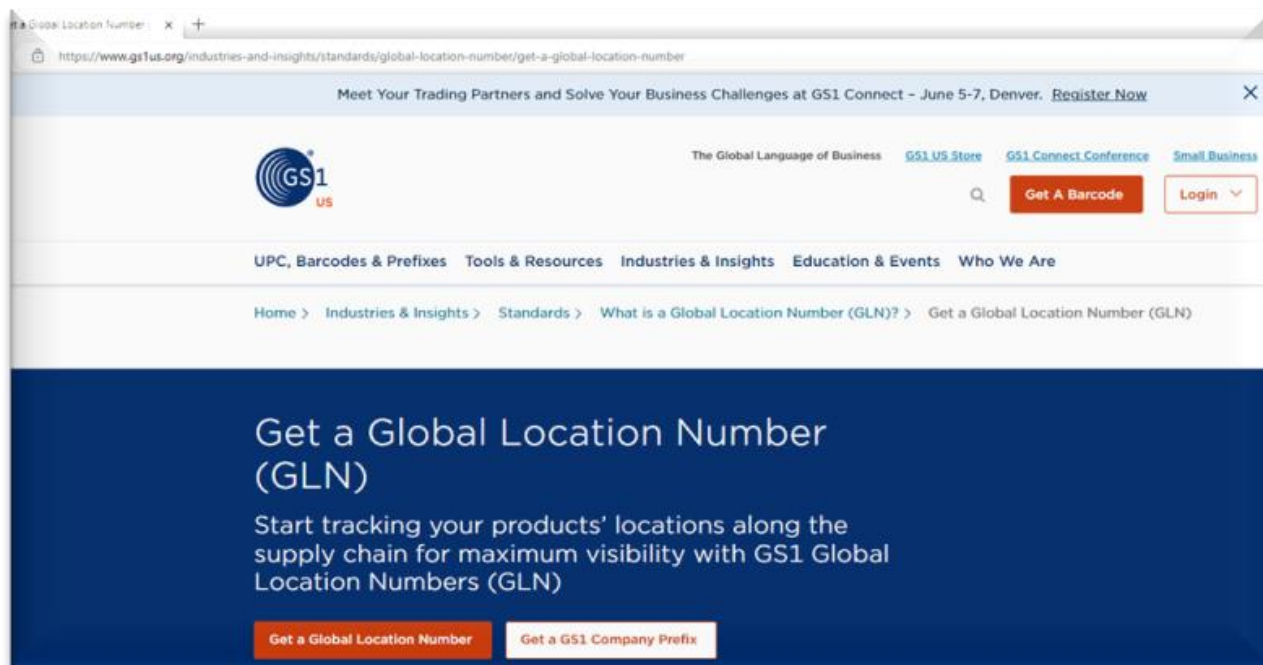
- Product tracing (*by 2015 lot-level, by 2023 package-level*)
- Product verification
 - Quarantine and investigation (steps for detection and response)
 - Notification, recordkeeping
- Product identification (*applied to product beginning 2017*)
- Wholesale distributor and third-party logistics provider standards for licensure
- Enhanced system (*electronic, interoperable system to trace products at the package-level by 2023*)
- Penalties
- National uniform policy

Best Practices

- Create Process in Place to verify licensure of all Authorized Trading Partners (ATP) at least annually
- Create Process to accept 3 T's and store data for 6 years
- Create Process for Product verification at package level
 - Quarantine and investigation (steps for detection and response)
 - Notification, recordkeeping
- Create Process for responding promptly with TI and TS upon request from regulatory bodies
- Create process for saleable returns

What Can I Do Now to Prepare?

- Obtain a GLN > visit the [GS1 website](https://www.gs1us.org)



Resources

- [Drug Supply Chain Security Act \(DSCSA\) | FDA](#)
- [Pharmacists: Utilize DSCSA Requirements to Protect Your Patients | FDA](#)
- [Pharmaceutical Tracing for pharmacies \(cardinalhealth.com\)](#)
- [Global Location Number - GS1US Ecommerce](#)

Drug Supply Chain Security Act (DSCSA) Updates

Compliance Policy Guidance on Enhanced Drug Distribution Security Requirements Under Section 582(g)(1) of the FD&C Act

FDA is announcing the availability of an immediately-in-effect compliance policy guidance, [Enhanced Drug Distribution Security Requirements Under Section 582\(g\)\(1\) of the Federal Food, Drug, and Cosmetic Act – Compliance Policies](#). This guidance describes FDA's compliance policies regarding enforcement of requirements for the interoperable, electronic, package-level product tracing (referred to as enhanced drug distribution security requirements) under section 582(g)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

Trading partners — primarily manufacturers, wholesale distributors, dispensers, and repackagers — are subject to requirements for enhanced drug distribution security under section 582(g)(1) of the FD&C Act, as added by the [Drug Supply Chain Security Act \(DSCSA\)](#). These requirements go into effect on November 27, 2023.

The guidance establishes a 1-year stabilization period to accommodate the additional time that industry may need to implement, troubleshoot, and mature their systems and processes while supporting the continued availability of products to patients. The stabilization period is not intended to provide, and should not be viewed as providing, a justification for delaying efforts by trading partners to implement the enhanced drug distribution security requirements under section 582(g)(1) of the FD&C Act.

This guidance clarifies that FDA does not intend to take action to enforce the enhanced drug distribution security requirements until November 27, 2024. In addition, FDA does not intend to take action to enforce section 582(g)(1)(B) of the FD&C Act with respect to product that is introduced in a transaction into commerce by the product's manufacturer or repackager before November 27, 2024, and for subsequent transactions of such product through the product's expiry.



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Thank you

Michael S. Kirkbride, Pharm. D, FNHIA, CHC
Chief Compliance and Ethics Officer, Vital
Care Infusion Services, LLC
mskirkbride@vitalcare.com

 PHARMACY



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